THE CLAIMS

What is claimed is:

1. A transdermal or transmucosal pharmaceutical formulation comprising:

at least one active agent; and

a solvent system present in an amount sufficient to solubilize the at least one active ingredient and characterized in that it includes:

(i) a pharmaceutically acceptable monoalkyl ether of diethylene glycol present in an amount of between about 1% and 30% by weight of the solvent system;

(ii) a pharmaceutically acceptable glycol present in an amount of between about 1% and 30% by weight of the solvent system, with the monoalkyl ether of diethylene glycol and glycol being present in a weight ratio of 10:1 to 2:1 or 1:2 to 1:10; and

(iii) a mixture of a C_2 to C_4 alcohol and water which mixture is present in an amount of between about 40% and 98% of the solvent system, wherein the C2 to C4 alcohol is present in an amount of about 5% to 80%of the mixture, and the water is present in an amount of about 20% to 95% of the mixture,

so that, compared to formulations containing the same components but in different amounts and ratios, the present solvent system (a) inhibits crystallization of the at least one active ingredient on a skin or mucosal surface of a mammal, (b) reduces or prevents transfer of the formulation to clothing or to another being, (c) modulates biodistribution of the at least one active agent within different layers of skin, (d) facilitates absorption of the at least one active agent by a skin or a mucosal surface of a mammal, or (e) provides a combination of one or more of (a) through (d).

2. The pharmaceutical formulation of claim 1, wherein the monoalkyl ether of diethylene glycol and the glycol are present in a weight ratio of 10:1 to 2:1.

3. The pharmaceutical formulation of claim 1, wherein the monoalkyl ether of diethylene glycol and the glycol are present in a weight ratio of 1:2 to 1:10.

4. The pharmaceutical formulation of claim 1, wherein the monoalkyl ether of diethylene glycol is selected from the group consisting of diethylene glycol monomethyl ether, and diethylene glycol monoethyl ether or mixtures thereof.

5. The pharmaceutical formulation of claim 1, wherein the glycol is selected from the group consisting of propylene glycol, dipropylene glycol or mixtures thereof.

6. The pharmaceutical formulation of claim 1, wherein the glycol modulates the capacity of diethylene glycol mono ethyl ether to build a skin depot.

7. The pharmaceutical formulation of claim 1, wherein the C_2 to C_4 alcohol is selected from the group consisting of ethanol, propanol, isopropanol, 1-butanol, 2-butanol, or mixtures thereof.

8. The pharmaceutical formulation of claim 1, further including a permeation enhancer present in an amount sufficient to increase permeability of the active agent across a dermal or mucosal surface of a mammal.

9. The pharmaceutical formulation of claim 1, wherein the formulation further includes lauryl alcohol or myristyl alcohol present in an amount from 0.5 to 2% by weight of the total formulation.

10. The pharmaceutical formulation of claim 1, wherein the at least one active ingredient includes a hormone or an anti-hormone.

11. The pharmaceutical formluation of claim 10, wherein the hormone or anti-hormone is an estrogen, an androgen, a progestogen, an anti-estrogen, an anti-androgen, or an anti-progestogen.

12. The pharmaceutical formulation of claim 11, wherein the estrogen is selected from the group consisting of colpormon, conjugated estrogenic hormones, equilenin, equilin, estradiol, estrone, ethinyl estradiol, estradiol benzoate, mestranol, moxestrol, mytatrienediol, quinestradiol, and quinestrol; and the androgen is selected from the group consisting of cloxotestosterone, fluoxymesterone, mestanolone, mesteronolone, 17-methyltestosterone, 17-α-methyltestosterone 3-cyclopentyl enol ether, norethandrolone, normethandrone, oxandrolone, oxymesterone, oxymetholone, prasterone, stanolone, stanolozol, testosterone, and tiomesterone.

13. The pharmaceutical formulation of claim 1, wherein the at least one active ingredient is a therapeutic agent selected from the group consisting of sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, ganglioplegics, local anaesthetics, myorelaxants, antihypertensives, diuretics, cardiotonics, anti-arythmics, anti-angina drugs, cerebral and peripheric vasodilatators, anti-migraine drugs, anti-histaminic drugs, anti-asthma drugs, thrombolytics, general anaesthetics, anxiolytics, antidepressants, neuroleptics, anti-convulsive drugs, hypothalamo-hypophysis regulators, hypo and hyperthyroidics, corticosteroids, glycemia regulators, hypolipidemia drugs, phosphocalcic metabolism regulators, antipyretics, anti-inflammatory drugs, anti-acids, antisecretive gastric drugs, laxatives, gastric mucosa protectors, gastric motricity modulators, bile salts adsorbants, chelators, gall stone dissolvants, anti-anemia drugs, cutaneous diseases drugs, antiparasit drugs, antibiotics, penicillins, cephalosporins, aminosids, polypeptides, sulfamides, diaminopyrimidines, tetracyclins, chloramphenicol, thiamphenicol, macrolides, vancomycin, teicoplanin, rifampicin, fusidic acid, 5-nitro-imidazoles, lincosamides, quinolones, anticancer drugs, anti virus drugs, and antifungus drugs.

14. The pharmaceutical formulation of claim 1, wherein the active agent is an anti-Parkinson drug, an anti-Alzheimer drug, or an analgesic drug.

15. The pharmaceutical formulation of claim 14, wherein the anti-Parkinson drug is selected from the group consisting of selegilline, trihexyphenidyl, tropatepione, bipeiden, procyclidine, benzatropine, orphenadrine, bornaprine, metixene, or levodopa, or a pharmaceutically acceptable salt thereof.

16. The pharmaceutical formulation of claim 14, wherein the anti-Parkinson drug is in combination with a decarboxylase inhibitor.

17. The pharmaceutical formulation of claim 14, wherein the anti-Alzheimer drug is galantamine, rivastigmine, donezepil, tacrine, or memantine, or a pharmaceutically acceptable salt thereof.

18. The pharmaceutical formulation of claim 14, wherein the analgesic is an opioid analgesic, and further wherein the opioid analgesic is fentanyl, alfentanil, sufentanil, or a pharmaceutically acceptable salt thereof.

19. The pharmaceutical formulation of claim 11, wherein at least one active agent is testosterone, the monoalkyl ether of diethylene glycol and the glycol are present in a weight ratio of 1:4, and the monoalkyl ether of diethylene glycol and the glycol in combination are present in an amount of a least 15% of the total formulation by weight.

20. The pharmaceutical formulation of claim 14, wherein the at least one active agent is selegilline or a pharmaceutically acceptable salt thereof, and the monoalkyl ether of diethylene glycol and the glycol are present in a weight ratio of 1:2 to 1:10.

21. The pharmaceutical formulation of claim 18, wherein the at least one active agent is fentanyl or a pharmaceutically acceptable salt thereof, and the monoalkyl ether of diethylene glycol is monoethyl ether of diethylene glycol, the glycol is propylene glycol, present in a weight ratio of 1:2 to 1:10.

22. The pharmaceutical formulation of claim 1, further comprising an agent selected from the group consisting of gelling agents; permeation enhancers, preservatives, antioxidants, buffers, humectants, sequestering agents, moisturizers, surfactants, emollients, and any combination thereof.

23. A method of delaying or inhibiting crystallization of an active agent in a transdermal or transmucosal pharmaceutical formulation, characterized in that the formulation comprises at least one active agent and a solvent system, the solvent system comprising a pharmaceutically acceptable monoalkyl ether of diethylene glycol and a glycol present in a weight ratio of 10:1 to 2:1 or 1:2 to 1:10.

24. The method of claim 23, wherein the monoalkyl ether of diethylene glycol and the glycol are present in an ratio of 10:1 to 2:1.

25. The method of claim 23, wherein the monoalkyl ether of diethylene glycol and the glycol are present in an amount of about.1:2 to 1:10.

26. The method of claim 23, wherein the monoalkyl ether of diethylene glycol and the glycol in combination are present in an amount of at least 15% and no more than 60% of the formulation.

27. The method of claim 13, wherein the solvent system further comprises a mixture of a C_2 to C_4 alcohol and water, the mixture present in an amount of between 40% and 98% of the solvent system.

28. The method of claim 23, wherein the C_2 to C_4 alcohol is present in an amount between 5% and 80% of the mixture, and the water is present in an amount between 20% and 95% of the mixture.

29. The method of claim 23, wherein the decrease or inhibition of crystallization of the active agent is sufficient to facilitate or increase absorption of the active agent across a skin or mucosal surface to which it is applied.

30. The method of claim 23, wherein the monoalkyl ether of diethylene glycol is selected from the group consisting of diethylene glycol monomethyl ether, and diethylene glycol monoethyl ether or mixtures thereof.

31. The method of claim 23, wherein the glycol is selected from the group consisting of propylene glycol, dipropylene glycol or mixtures thereof.

32. The method of claim 23, which further comprises providing a permeation enhancer present in an amount sufficient to increase permeability of the active agent across a dermal or mucosal surface of a mammal.

33. The method of claim 23, wherein the formulation further includes lauryl alcohol or myristyl alcohol present in an amount from 0.5 to 2% by weight of the total formulation.

34. The method of claim 23, characterized in that the C_2 to C_4 alcohol is selected from the group consisting of ethanol, propanol, isopropanol, 1-butanol, 2-butanol, or mixtures thereof.

35. The method of claim 23, characterized in that the at least one active ingredient is selected from the group including sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, ganglioplegics, myorelaxants, antihypertensives, diuretics, cardiotonics, anti-arythmics, anti-angina drugs, cerebral and peripheric vasodilatators, anti-migraine drugs, anti-histaminic drugs, anti-asthma drugs, thrombolytics, general anaesthetics, anxiolytics, antidepressants, neuroleptics, anti-convulsive drugs, hypothalamo-hypophysis regulators, hypo and hyperthyroidics, corticosteroids, glycemia regulators, hypolipidemia drugs, phosphocalcic metabolism regulators, antipyretics, anti-inflammatory drugs, anti-acids, antisecretive gastric drugs, laxatives, gastric mucosa protectors, gastric motricity modulators, bile salts adsorbants, chelators, gall stone dissolvants, anti-anemia drugs, cutaneous diseases drugs, antiparasit drugs, antibiotics, penicillins, cephalosporins, aminosids, polypeptides, sulfamides, diaminopyrimidines, tetracyclins, chloramphenicol, thiamphenicol, macrolides, vancomycin, teicoplanin, rifampicin, fusidic acid, 5-nitro-imidazoles, lincosamides, quinolones, anticancer drugs, anti virus drugs, and antifungus drugs.

36. The method of claim 1, wherein the at least one active ingredient includes a hormone or an antihormone.

37. The method of claim 36, wherein the hormone or anti-hormone is an estrogen, an androgen, a progestogen, an anti-estrogen, or an anti-androgen, or an anti progestogen.

38. The method of claim 1, wherein the active agent is an anti-Parkinson drug, an anti-Alzheimer drug, or an analgesic.

39. The method of claim 38, wherein the anti-Parkinson drug is selected from the group consisting of selegilline, trihexyphenidyl, tropatepione, bipeiden, procyclidine, benzatropine, orphenadrine, bornaprine, metixene, or levodopa, or a pharmaceutically acceptable salt thereof.

40. The method of claim 38, wherein the anti-Parkinson drug is in combination with a decarboxylase inhibitor.

41. The method of claim 38, wherein the anti-Alzheimer drug is galantamine, rivastigmine, donezepil, tacrine, or memantine, or a pharmaceutically acceptable salt thereof.

42. The method of claim 38, wherein the analgesic is an opioid analgesic, and further wherein the opioid analgesic is fentanyl, alfentanil, sufentanil, or a pharmaceutically acceptable salt thereof.

43. The method of claim 42, wherein the active agent is fentanyl, the monoalkyl ether of diethylene glycol is monoethyl ether of diethylene glycol, the glycol is propylene glycol, present in a weight ratio of 1:2 to 1:10.

44. The method of claim 39, characterized in that the active agent is selegilline hydrochloride, the monoalkyl ether of diethylene glycol and the glycol are present in a weight ratio of 1:2 to 1:10.

45. The method of claim 37, wherein at least one active agent is testosterone, the monoalkyl ether of diethylene glycol and the glycol are present in a weight ratio of 1:4, and the monoalkyl ether of diethylene glycol and the glycol in combination are present in an amount of a least 15% of the total formulation by weight.